DEC 1 7 2001

SALIMETRICS LLC

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Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K011323.

I. General Information

Submitter:

Eve Schwartz
Salimetrics, LCC
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Date of 510(k) preparation:

Device Trade Name: HS(high sensitivity) Salivary Cortisol Enzyme Immunoassay

Generic Name: Immunoassay for the in vitro quantitative determination of cortisol in saliva

Predicate Device: The HS Salivary Cortisol EIA is substantially equivalent to the Diagnostic Systems Laboratory Active Cortisol EIA, which was approved by FDA (K850141) for IVD use.

VI. Intended Use

Salimetrics HS-Cortisol kit is a competitive immunoassay specifically designed for the quantitative *in vitro* diagnostic measurement of salivary cortisol. It is not intended for use with serum/plasma.

III. Device Description

Test Principle- A microtitre plate is coated with rabbit antibodies to cortisol. Cortisol in standards and unknowns compete with cortisol linked to horseradish peroxidase for the antibody binding sites. After incubation, unbound components are washed away. Bound cortisol peroxidase is measured by the reaction of the peroxidase enzyme on the substrate tetramethylbenzidine (TMB). This reaction produces a blue color. A yellow color is formed after stopping the reaction with sulfuric acid. Optical density is read on a standard plate reader at 450 nm. The amount of cortisol peroxidase detected is inversely proportional to the amount of cortisol present. The optical density readings of the calibrators are used to form a standard curve to which the optical densities of the controls and samples are compared.

Kit Description- The kit consists of an antibody coated 96 well plate, a calibrator at a concentration of 1.8 µg/dL of NIST(National Institute of Standards and Technology) cortisol, two controls representing a high and low level of salivary cortisol, the enzyme conjugate (1600X concentrate), assay diluent containing a pH indicator, wash buffer(10X concentrate), tetramethylbenzidine substrate solution, stop solution, and kit insert.

IV. Prior Marketing History

The HS Salivary Cortisol EIA has been sold as a research tool since November of 1998. There have been no withdrawals of this device from any country related to safety and effectiveness. To date, this kit has not been marketed for diagnostic use.

VII. Contraindications, Warnings and Precautions

- This kit is designed to measure cortisol levels in saliva and should not be used to measure serum or plasma levels.
- A pH value should be obtained on samples that appear yellow or purple after assay diluent is added and the plate is mixed. Samples with pH values > than 9 or < 3.5 should be recollected.
- Particulate matter may affect antibody binding. Pipette only clear saliva into wells. Saliva may be filtered through cotton to eliminate particulate matter.
- Saliva samples contaminated with blood may give false results.
- Saliva collection and handling recommendations are presented in the kit insert.

VIII. Comparison to Predicate Device

Correlation with Serum and Relationship to Predicate Device

The correlation between saliva and serum is highly significant, r (64) = .89, $p < .0001$. The relationship between the HS Cortisol Salivary EIA and the serum cortisol predicate device, determined by linear regression is y(serum µg/dL)= 5.177+15.132x(saliva µg/dL).

List of similarities and differences between the HS salivary Cortisol EIA and the predicate device

Table 1 List of assay Characteristics

Device Characteristic	**HS Salivary Cortisol EIA**	**Predicate Device**
Basic Principal	Competitive Solid Phase Immunoassay	Competitive Solid Phase Immunoassay
Calibrator matrix	Saliva-like matrix	Serum matrix
Tracer	Horseradish Peroxidase linked to cortisol	Horseradish Peroxidase linked to cortisol
Substrate	Tetramethylbenzidine(TMB)	Tetramethylbenzidine(TMB)
Primary Antibody	goat anti rabbit	goat anti rabbit
Calibrator Range	0.007 - 1.800 µg/dL	0.5 - 60 µg/dL
Sample Type	saliva	serum or plasma
Instrumentation	standard plate reader	standard plate reader
Intra-assay Precision	Coefficient of variation < 6%	Coefficient of variation < 11%
Inter-assay Precision	Coefficient of variation < 11%	Coefficient of variation <12%
Sensitivity	<0.007 µg/dL	0.1 µg/dL
Linearity	84 –105 % recovery	81-119% recovery
Recovery	84-115%	93-124
Control Levels	1.000 µg/dL and 0.100 µg/dL	20 µg/dL and 4 µg/dL

VI. Conclusion

The data presented in the 510(k) demonstrates that cortisol can be measured in the HS Salivary Cortisol EIA with comparable accuracy in saliva when compared to the serum predicate device. Saliva cortisol values measured with the HS Salivary Cortisol EIA correlate well with serum cortisol values. There is also a large amount of supporting literature that indicates cortisol can be measured accurately in saliva when samples are collected and stored in an appropriate manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Eve Schwartz
VP of Operations
Salimetrics LLC.
P.O. Box 395
State College, PA 16801-0395

Re: k011323
Trade/Device Name: HS Salivary Cortisol Enzyme Immunoassay Kit
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: NHG
Dated: October 10, 2001
Received: October 12, 2001

Dear Ms. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) number: K011323

Device Name: HS Salivary Cortisol Enzyme Immunoassay Kit

Indications for Use:

Salimetrics HS-Cortisol kit is a competitive immunoassay specifically designed for the quantitative *in vitro* diagnostic measurement of salivary cortisol. This kit may be used to measure adrenal cortical function and as a screen for Cushing's and Addison's disease. Saliva cortisol accurately reflects the amount of serum cortisol in the circulation. This kit is not intended for use with serum or plasma samples.

Thomas C. Trask for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011323

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___